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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
SWITZER, JULIET CAROLINE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,415	HASHIMOTO ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-25,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/15/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/02;1/06;2/05;*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *also ids 8/02 and 7/05*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, with a further election of SEQ ID NO: 1 and a probe with a base sequence represented by the 415-425th positions of SEQ ID NO: 37 as the first and second probes in the reply filed on 12/21/05 is acknowledged. The traversal is on the ground(s) that there would be no burden to examine all inventions. This is not found persuasive because this is a 371 and the standard is not a standard of burden, but instead of unity of invention, as discussed in the restriction requirement. This is not found persuasive because under the PCT rules, a showing of lack of unity is required for proper restriction of claims and such a showing has been made. Furthermore, however, it would indeed pose a serious burden on the examiner to examine the claims all together since each group and each sequence requires a different field of search.

MPEP 801 states,

> "This chapter is limited to a discussion of the subject of restriction and double patenting under Title 35 of the United States Code and Title 37 of the Code of Federal Regulations as it relates to national applications filed under 35 U.S.C. 111(a). **The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority, and in applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in Chapter 1800** (emphasis added)."

Referring to Chapter 1800, MPEP 1893.03(d) states,

> "The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept. A group of inventions is considered linked to form a single general

> inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes **over the prior art** (emphasis added)."

In the instant case, there is not unity of invention between the products of group II and the method claims because the products do not provide an advance in view of the prior art as indicated in the restriction requirement and as discussed in the art rejections set forth in this office action. The requirement is still deemed proper and is therefore made FINAL.

2. Upon further reconsideration, however, SOME of the probes recited in claim 23 have been rejoined. Namely, second probes identified in the claims which are fragments of SEQ ID NO: 37, 38, 39, or 40 are rejoined (probes identified as (aa420), (ba420), (ca420), (da420), (ac420), (bc420), (cc420), (dc420), (at420), (bt420), (ct420), (dt420), (ag420), (bg420), (cg420), and (dg420)). These probes are all different variants of the MxA gene promoter which have different nucleotides at position 420 for the detection of a polymorphism at a position –123 of the MxA gene promoter. The claim was examined so as to consider that the second probe must comprise at least one sequence selected from this group.

Specification

3. The disclosure is objected to because of the following informalities: The specification, at page 36 states "The base sequences represented by SEQ ID NO: 37-40 are identical except for the base of the 425th position." However, comparing these sequences, they are identical except for the base of the 420th position. Further, it is noted that at position 420, SEQ ID NO: 37 has a thymine, SEQ ID NO: 38 has a guanine, SEQ ID NO: 39 has an adenine and SEQ ID NO: 40 has a cytosine.

4. Also, on page 40 in line 4, the specification refers to SEQ ID NO: 37 where the 425th position is adenine. However, it appears from the sequence listing and the disclosure that this should refer to the 420th position since this is the polymorphic position within SEQ ID NO: 37. But again, it is noted, that this position is thymine in SEQ ID NO: 37. Even if applicant intended to refer to the 425th position, this is not adenine in SEQ ID NO: 37-40, it is guanine in all four sequences.

Appropriate correction is required.

Claim Objections

5. Claim 23 is objected to because it contains non-elected subject matter. Deletion of the non-elected sequences is required prior to allowance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 19, 23, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "said medicinal agent" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Neither claim 18 nor claim 19 previously recite a "medicinal agent."

In claim 23, the language used to define the first and second probes sequences is unclear. First, the use of the terminology "represented by" SEQ ID NO: 1 is confusing because it is not clear for a sequence to be "represented by" a particular SEQ ID NO. For example, it is not clear

if applicant intends for the claim to include a sequence comprising SEQ ID NO: 1 in it's entirety, a sequence consisting of SEQ ID NO: 1or if the "sequences represented by" also include fragments of SEQ ID NO: 1. Clarification of the claim language is required. Furthermore, it is unclear what applicant intends when they recite "a complementary sequence" since it is not clear if this language means a sequence or subsequence with any level of complementarity (i.e. as little as one or two nucleotides complementary to SEQ ID NO: 1) or if applicant intends that this recitation encompass "the complement" of SEQ ID NO: 1 in its entirety. In the description of the second probes, this same language is used and is confusing. Further, in the description of probes (ba420), (bt420), (bc420), and (bg420), the recitation "except for the base of the 420th position" is unclear because it is not clear if this language means that since the base at position 420 in SEQ ID NO: 37, for example is "G" then "the base" is "G" and probe (ba420) means that no "G" in SEQ ID NO: 37 can be modified, or if applicant intends that the nucleotide at position 420 cannot be modified. If applicant intends the latter, it is not clear how one could identify "the base at position 420" if any number of nucleotides on either side of the position can be modified or deleted or nucleotides can be added on, as then this position might not be 420, and the nucleotide context might be different.

Claim 23 is also indefinite over the recitation "a first probe" which is singular, but the probe comprises "at least one sequence selected from" which clearly implies that more than one of the following sequences can be in the "first probe." However, it is not clear if the claim intends then, that the first probe be one molecule which more than one of the choices given, or if multiple different molecules can be part of the "second probe." Likewise the description of the

second probe is confusing. The claim would be clearer to recite a first probe set and a second probe set.

Claims 24 and 25 are indefinite because they refer to the probe immobilized chips of claims 24 and 25, but the recite an additional method step. It is not clear how these claims further limit the product claims they depend from.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 18, 19, 22, 24, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Maertens et al. (US 5846704).

Maertens et al. teach a probe-immobilized substrate comprising membrane having attached thereupon a first probe immobilized for detecting the presence of a specific nucleic acid, and a second probe immobilized on the substrate and having a different base sequence from the first probe, for detecting the presence of a specific nucleic acid of an individual wherein said nucleic acid of said individual is associated with responsiveness to a treatment for a disease. Namely, Maertens et al. teach a membrane having thereupon selected probes which are specific of HCV types (Col. 25, line 62-Col. 26, line 12; Table 4). Any one of these probes falls within the scope of the "first probe" required by claim 18. Further, most of the probes are also designed

to detect the presence of specific nucleic acid sequence of an individual HCV molecule wherein said nucleic acid identifies the subtype of the individual molecule, and it is an inherent property of HCV that the genotype (as determined by nucleic acid sequence) is related to response to interferon treatment (Col. 2, lines 17-21; Col. 25, line 62-Col. 26, line 12). Regarding claim 24, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

Regarding claim 32, Maertens et al. teach a method comprising the step of immobilizing the probes on a substrate (Col. 25, line 62-Col. 26, line 12). Regarding claim 33, the substrate is a membrane, which is a porous material.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 18, 19, 20, 22, 23, 24, 25, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al. (US 5846704) in view of either Hijikata et al. (Intervirology 2000, as cited in IDS).

Maertens et al. teach a probe-immobilized substrate comprising membrane having attached thereupon a first probe immobilized for detecting the presence of a specific nucleic acid, and a second probe immobilized on the substrate and having a different base sequence from the first probe, for detecting the presence of a specific nucleic acid of an individual wherein said nucleic acid of said individual is associated with responsiveness to a treatment for a disease. Namely, Maertens et al. teach a membrane having thereupon selected probes which are specific of HCV types (Col. 25, line 62-Col. 26, line 12; Table 4). Any one of these probes falls within the scope of the "first probe" required by claim 18. Further, Maertens et al. teach that response to interferon therapy is predicted by HCV genotype (Col. 2, lines 17-21; Col. 25, line 62-Col. 26, line 12). Regarding claim 24, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

Regarding claim 32, Maertens et al. teach a method comprising the step of immobilizing the probes on a substrate (Col. 25, line 62-Col. 26, line 12). Regarding claim 33, the substrate is a membrane, which is a porous material.

Maertens et al. does not teach an embodiment wherein the second probe is to a different organism than the first probe or wherein the nucleic acid of the individual is the promoter region of MxA.

Hijikata et al. (2000, as cited in the IDS) teach a correlation between a polymorphism in the MxA gene promoter and patient response to HCV therapy, namely to interferon therapy. Thus, it would have been prima facie obvious at the time the invention was made to have included probes for detecting and genotyping the human MXA gene promoter on the substrate taught by Maertens et al. for the benefit of providing a single substrate that would be useful for genotyping both a patient's viral genotype and their MxA genotype for use in prediction of response to interferon therapy.

Regarding claim 23, Maertens et al. does not specifically teach the inclusion of a sequence comprising instant SEQ ID NO: 1 on their substrates. Maertens et al. do teach a "Universal" oligonucleotide which comprises instant SEQ ID NO: 1, namely their SEQ ID NO: 1 (see Table 4, for example). Further, they teach the inclusion of other "universal" oligonucleotides on their substrates, see, for example, the list of oligonucleotides in Table 5. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention taught by Maertens et al. so as to have included their universal oligonucleotide on the substrate. One would have been motivated to include this probe for the purpose of providing an additional universal probe for the detection of HCV in a sample. Further, regarding the second probe of claim 23, probe instant SEQ ID NO: 40 has a "C" at position 420, which is the nucleotide which was known to be at this position in the human MxA gene promoter (as evidenced in GenBank accession X55639, referenced by Hijikata et al. p. 125). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to put a nucleic acid encoding SEQ ID NO: 40, or SEQ ID NO: 40 modified at position 455 (which is equivalent to position –88, see Fig. 1 of Hijikata et al.) on the

substrate taught by Maertens et al. and their MxA genotype for use in prediction of response to interferon therapy. Regarding claims 24 and 25, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

13. Claims 18, 19, 21, 22, 24, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al. (US 5846704) in view of either Matsushita et al. (Journal of Hepatology, 1998, as cited in IDS).

Maertens et al. teach a probe-immobilized substrate comprising membrane having attached thereupon a first probe immobilized for detecting the presence of a specific nucleic acid, and a second probe immobilized on the substrate and having a different base sequence from the first probe, for detecting the presence of a specific nucleic acid of an individual wherein said nucleic acid of said individual is associated with responsiveness to a treatment for a disease. Namely, Maertens et al. teach a membrane having thereupon selected probes which are specific of HCV types (Col. 25, line 62-Col. 26, line 12; Table 4). Any one of these probes falls within the scope of the "first probe" required by claim 18. Further, Maertens et al. teach that response to interferon therapy is predicted by HCV genotype (Col. 2, lines 17-21; Col. 25, line 62-Col. 26, line 12). Regarding claim 24, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

Regarding claim 32, Maertens et al. teach a method comprising the step of immobilizing the probes on a substrate (Col. 25, line 62-Col. 26, line 12). Regarding claim 33, the substrate is a membrane, which is a porous material.

Maertens et al. does not teach an embodiment wherein the second probe is to a different organism than the first probe or wherein the nucleic acid of the individual is the gene encoding MBL.

Matsushita et al. teach a correlation between a polymorphism in the MBL gene and patient response to HCV therapy, namely to interferon therapy (abstract and throughout). Thus, it would have been prima facie obvious at the time the invention was made to have included probes for detecting and genotyping the human MBL gene on the substrate taught by Maertens et al. for the benefit of providing a single substrate that would be useful for genotyping both a patient's viral genotype and their MBL genotype for use in prediction of response to interferon therapy.

14. Claims 18, 19, 20, 22, 23, 24, 25, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maertens et al. (US 5846704) in view of either Hijikata et al. (Intervirology 2001, as cited in IDS).

Maertens et al. teach a probe-immobilized substrate comprising membrane having attached thereupon a first probe immobilized for detecting the presence of a specific nucleic acid, and a second probe immobilized on the substrate and having a different base sequence from the first probe, for detecting the presence of a specific nucleic acid of an individual wherein said nucleic acid of said individual is associated with responsiveness to a treatment for a disease. Namely, Maertens et al. teach a membrane having thereupon selected probes which are specific of HCV types (Col. 25, line 62-Col. 26, line 12; Table 4). Any one of these probes falls within the scope of the "first probe" required by claim 18. Further, Maertens et al. teach that response

to interferon therapy is predicted by HCV genotype (as determined by nucleic acid sequence) is related to response to interferon treatment (Col. 2, lines 17-21; Col. 25, line 62-Col. 26, line 12). Regarding claim 24, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

Regarding claim 32, Maertens et al. teach a method comprising the step of immobilizing the probes on a substrate (Col. 25, line 62-Col. 26, line 12). Regarding claim 33, the substrate is a membrane, which is a porous material.

Maertens et al. does not teach an embodiment wherein the second probe is to a different organism than the first probe or wherein the nucleic acid of the individual is the promoter region of MxA.

Hijikata et al. (2000, as cited in the IDS) teach a correlation between a polymorphism at the –123 position of the MxA gene promoter and patient response to HCV therapy, namely to interferon therapy. Thus, it would have been prima facie obvious at the time the invention was made to have included probes for detecting and genotyping the human MXA gene promoter on the substrate taught by Maertens et al. for the benefit of providing a single substrate that would be useful for genotyping both a patient's viral genotype and their MxA genotype for use in prediction of response to interferon therapy.

Regarding claim 23, Maertens et al. does not specifically teach the inclusion of a sequence comprising instant SEQ ID NO: 1 on their substrates. Maertens et al. do teach a "Universal" oligonucleotide which comprises instant SEQ ID NO: 1, namely their SEQ ID NO: 1 (see Table 4, for example). Further, they teach the inclusion of other "universal" oligonucleotides on their substrates, see, for example, the list of oligonucleotides in Table 5. It

would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention taught by Maertens et al. so as to have included their universal oligonucleotide on the substrate. One would have been motivated to include this probe for the purpose of providing an additional universal probe for the detection of HCV in a sample. Further, regarding the second probe of claim 23, this probe can be selected from one of sixteen different choices given in the claim (see rejoinder above). Probes (ct420) and (cg420), for example, contain portions of the MxA gene promoter that overlap with the polymorphism taught at position –123 by Hijikata et al. and have an A and a C, respectively, at that position. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included probes which comprise the polymorphic position at –123 of the MxA gene for the purpose of detecting this genetic polymorphism. Regarding claims 25, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

Thus, in view of the prior art, the claimed invention is prima facie obvious.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 18, 19, 20, 22, 23, 24, 25, 32, and 33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6783935 in view of Maertens et al.

The issued patent claims in US 6783935 teach an oligonucleotide comprising nucleotides 415-425 of instant SEQ ID NO: 39 and 40, as instant SEQ ID NO: 1 of that patent comprises these nucleotides at the same position, wherein the nucleotide at position 420 is an "M," and the "M" symbol means a "C" or and "A" is present at that position. The claims of the patent further teach that this molecule is "suitable for predicting the efficacy of interferon therapy." Further, this sequence is the MxA gene promoter.

The patent does not claim this nucleotide on a substrate alone, or in combination with another nucleic acid that is for detecting the presence of a specific nucleic acid of a pathogenic microorganism.

Maertens et al. teach a probe-immobilized substrate comprising membrane having attached thereupon a first probe immobilized for detecting the presence of a specific nucleic acid, and a second probe immobilized on the substrate and having a different base sequence from the first probe, for detecting the presence of a specific nucleic acid of an individual wherein said nucleic acid of said individual is associated with responsiveness to a treatment for a disease. Namely, Maertens et al. teach a membrane having thereupon selected probes which are specific

of HCV types (Col. 25, line 62-Col. 26, line 12; Table 4). Any one of these probes falls within the scope of the "first probe" required by claim 18. Further, Maertens et al. teach that response to interferon therapy is predicted by HCV genotype (Col. 2, lines 17-21; Col. 25, line 62-Col. 26, line 12). Regarding claim 24, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

Regarding claim 32, Maertens et al. teach a method comprising the step of immobilizing the probes on a substrate (Col. 25, line 62-Col. 26, line 12). Regarding claim 33, the substrate is a membrane, which is a porous material.

It would have been prima facie obvious at the time the invention was made to have included the claimed nucleic acid sequence on the solid support taught by Maertens et al. One would have been motivated to include this sequence on the support taught by Maertens et al. in order to have provided a tool to genotype an additional nucleic acid sequence that is useful for predicting response to interferon therapy. Regarding claim 23, Maertens et al. does not specifically teach the inclusion of a sequence comprising instant SEQ ID NO: 1 on their substrates. Maertens et al. do teach a "Universal" oligonucleotide which comprises instant SEQ ID NO: 1, namely their SEQ ID NO: 1 (see Table 4, for example). Further, they teach the inclusion of other "universal" oligonucleotides on their substrates, see, for example, the list of oligonucleotides in Table 5. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention taught by Maertens et al. so as to have included their universal oligonucleotide on the substrate. One would have been

motivated to include this probe for the purpose of providing an additional universal probe for the detection of HCV in a sample.

17. Claims 18, 19, 20, 22, 23, 24, 25, 32, and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 and 25-28 of copending Application No. 10/633659 in view of Maertens et al. This is a provisional obviousness-type double patenting rejection.

The claims of the application set include a polynucleotide immobilized on a surface which is a sequence that is associated with responsiveness to interferon treatment. Namely, the claims teach an oligonucleotide comprising nucleotides 415-425 of instant SEQ ID NO: 39 and 40, as instant SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 4 of that application comprise these nucleotides at the same position, wherein the nucleotide at position 420 is an "M," and the "M" symbol means a "C" or and "A" is present at that position. The claims of the patent further teach that these supports can be part of "a gene detecting apparatus for detecting validity of interferon therapy (see claim 25, for example)." Further, this sequence is the MxA gene promoter.

The application does not claim this solid support in combination with another nucleic acid that is for detecting the presence of a specific nucleic acid of a pathogenic microorganism.

Maertens et al. teach a probe-immobilized substrate comprising membrane having attached thereupon a first probe immobilized for detecting the presence of a specific nucleic acid, and a second probe immobilized on the substrate and having a different base sequence from the first probe, for detecting the presence of a specific nucleic acid of an individual wherein said nucleic acid of said individual is associated with responsiveness to a treatment for a disease.

Namely, Maertens et al. teach a membrane having thereupon selected probes which are specific of HCV types (Col. 25, line 62-Col. 26, line 12; Table 4). Any one of these probes falls within the scope of the "first probe" required by claim 18. Further, Maertens et al. teach that response to interferon therapy is predicted by HCV genotype (Col. 2, lines 17-21; Col. 25, line 62-Col. 26, line 12). Regarding claim 24, this rejection is applied to this claim because the claim recites a method step, but does not set forth any apparent further structural limitation for the claimed substrate.

Regarding claim 32, Maertens et al. teach a method comprising the step of immobilizing the probes on a substrate (Col. 25, line 62-Col. 26, line 12). Regarding claim 33, the substrate is a membrane, which is a porous material.

It would have been prima facie obvious at the time the invention was made to have included the claimed nucleic acid sequence on the solid support taught by Maertens et al. One would have been motivated to include this sequence on the support taught by Maertens et al. in order to have provided a tool to genotype an additional nucleic acid sequence that is useful for predicting response to interferon therapy. Regarding claim 23, Maertens et al. does not specifically teach the inclusion of a sequence comprising instant SEQ ID NO: 1 on their substrates. Maertens et al. do teach a "Universal" oligonucleotide which comprises instant SEQ ID NO: 1, namely their SEQ ID NO: 1 (see Table 4, for example). Further, they teach the inclusion of other "universal" oligonucleotides on their substrates, see, for example, the list of oligonucleotides in Table 5. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention taught by Maertens et al. so as to have included their universal oligonucleotide on the substrate. One would have been

motivated to include this probe for the purpose of providing an additional universal probe for the detection of HCV in a sample.

Allowable Subject Matter

18. It is noted that the authorship of the Hijikata et al. (2001) reference is distinct from the inventorship of the instant application, but includes some inventors of the instant application. If the rejection based on this reference were overcome by the removal of this reference, for example by filing a 132 Katz-type declaration, and if all pending double patenting rejections are overcome, a claim as follows would be allowable:

A probe-immobilized substrate comprising:

a substrate

a first probe set immobilized on the substrate comprising at least one of SEQ ID NO: 1 or the complement of SEQ ID NO: 1;

a second probe set immobilized on the substrate comprising at least one of the following:

(a) an oligonucleotide probe comprising SEQ ID NO: 37;

(b) an oligonucleotide probe comprising nucleotides 415-425 of SEQ ID NO: 37;

(c) an oligonucleotide probe comprising SEQ ID NO: 38;

(d) an oligonucleotide probe comprising nucleotides 415-425 of SEQ ID NO: 38;

(e) an oligonucleotide probe comprising SEQ ID NO: 40;

(f) an oligonucleotide probe comprising nucleotides 415-425 of SEQ ID NO: 40;

(e) an oligonucleotide probe that is the complement of any one of (a)-(f).

Conclusion

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Thursday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached by calling (571) 272-0735.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

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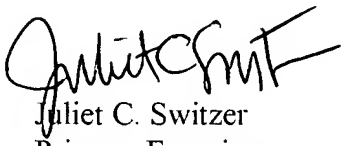

Juliet C. Switzer
Primary Examiner
Art Unit 1634

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